

Original Research Paper

Laboratory Errors and Clinical Diagnosis

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A laboratory test is a medical procedure that involves testing a sample of blood, urine, or other tissues or substances in the body. Some laboratory tests are precise, reliable indicators of specific health problems while others provide more general information that simply gives doctors clues to possible health problems. Information obtained from laboratory tests may help doctors decide what her other tests or procedures are needed to make a diagnosis or to develop or revise a previously diagnosed natient's	

whether other tests or procedures are needed to make a diagnosis or to develop or revise a previously diagnosed patient's treatment plan. Clinical labs are Focus on finding and fixing pre and post analytical errors. The purpose of the Review what we discussed in this article is to systematically examine the information of case details, sample collection procedures and assays that optimize the use of these additional case reviews inorder to reduce interpretive errors or descrepancies. Clinical Laboratory errors can no longer be seen as inevitable, but it can be actively streamlined and prevented.

KEYWORDS

Laboratory Errors, Sample collection, Pre analytical Errors, Diagnosis.

INTRODUCTION

Symptoms generally lead to blood tests and radiographs, depending on the situation. Blood tests are a key step in the evaluation. Blood tests interpretation should be done by a medical professional. A laboratory test is a medical procedure that involves testing a sample of blood, urine, or other tissues or substances in the body. Such tests have a variety of uses. They are often used as part of a routine checkup to identify possible changes in a person's health before any symptoms occur. Laboratory tests also play an important role in diagnosis when a person has symptoms. In addition, tests may be used to help plan a patient's treatment, evaluate the response to treatment, or monitor the course of the disease over time.

Laboratory test samples are analyzed to determine whether the test results fall within normal ranges. They also may be checked for changes from previous tests. Normal test values are usually given as a range, rather than as a specific number, because normal values vary from person to person. What is normal for one person may not be normal for another person. Many factors (including the patient's sex, age, race, medical history, and general health) can affect test results. Other factors that sometimes affect test results include specific foods, drugs the patient is taking, how closely the patient follows preparatory instructions, and variations in laboratory techniques. It is also common for normal ranges to vary somewhat from laboratory to laboratory[1].

Some laboratory tests are precise, reliable indicators of specific health problems while others provide more general information that simply gives doctors clues to possible health problems. Information obtained from laboratory tests may help doctors decide whether other tests or procedures are needed to make a diagnosis or to develop or revise a previously diagnosed patient's treatment plan[2]. All laboratory test results must be interpreted in the context of the overall health of the patient and are generally used along with other exams or tests. The doctor who is familiar with the patient's medical history and current condition is in the best position to interpret that person's test results and explain their implications. Patients are encouraged to discuss questions or concerns about laboratory test results with the doctor. The normal values for blood tests can be different from lab to lab. Blood tests

can have false positives and false negatives. Interpretation of blood tests takes knowledge of the underlying disease process and experience[3]. Blood tests should be interpreted by health care providers. Sometimes blood tests need to be confirmed if there is a question about the reliability of the result. Flash-Med is a resource for questions and answers about blood tests. Learn about the significance of abnormal blood tests and interpreting blood test results. So our aim is discussed in this review article Laboratory patient identification, sample collection, Quantity of the sample, Laboratory requisition information and Diagnosis. The purpose of the Review article is to discuss current models that describe the testing process, and then propose a different approach to facilitate the reduction of diagnostic errors and harm related to diagnostic testing.

DISCUSSION

Clinical laboratories typically assess their performance based on measures of laboratory efficiency and internal quality rather than patient outcomes. For example, turnaround times typically measure in-laboratory sample receipt to the issuance of results. Measures of quality defects generally pertain to those that reduce productivity (e.g. sample haemolysis, insufficient quantity of sample, missing sample identification, etc.). Failures in the ordering of laboratory tests and the application of laboratory test results are major contributors to diagnostic errors, along with residual problems in test performance procedures[4]. There are many factors to consider when collecting lab specimens; and prior to diagnostic tests. Preparation of the patient prior to the test or diagnostic measure is vitally important to the results of the test. Many laboratory tests and diagnostic tests do not require any extensive preparation. However, the nurse should pay very close attention to those tests that do require preparation. The type of blood sample needed is very important. The type of blood depends upon the test ordered. Different types of blood samples include Whole Blood, Plasma, Serum, Venous Blood, Capillary, or Arterial Blood. In most common lab tests, venous blood is used. The lab will then extract serum or plasma, depending upon the test to be performed. Venous blood is a good indicator of the physiological conditions throughout the body. It is also relatively easy to obtain. Therefore, venous blood is used most frequently for testing.

Be sure to collect the specimen in the correct blood tube. Certain blood specimens must be collected in tubes with no anticoagulant. Some specimens must be collected in a tube with anticoagulants. Be sure to handle the specimens correctly. Some blood specimens must be gently mixed with the anticoagulant in the tube. Some blood specimens must not be shaken in the tube. In addition, the collection procedure itself may cause problems. Hemoconcentration may occur due to prolonged tourniquet constriction. Hemodilution may occur due to drawing the blood sample from the same arm with an intravenous infusion of fluids running. Hemolysis may occur due to rough handling of the sample or from drawing the blood through a small-gauge needle [5]. Arterial blood samples are necessary for obtaining the blood pH and the levels of dissolved Oxygen and Carbon Dioxide in the blood. Arterial blood sampling will be discussed later in the text in detail. However, it is well known that arterial sampling carries a higher risk to the patient than does venous sampling. Arterial puncturing carries a higher risk of hematoma and arterial spasm and hemorrhage.

Patient Identification:

Probably the most important factors regarding laboratory tests and/or procedures are patient identification and sample identification. The nurse should be very careful to properly identify the patient and the specimens obtained. If the nurse is not going to directly gather the specimen, then the nurse should be sure the lab tech has the correct patient [6]. Be sure that the tech has the correct room number of the patient. Be sure to inform the lab of any changes in room numbers. The lab requisition slip may have a room number that is incorrect because the patient was moved to another room. This happens very commonly. However, the lab tech is supposed to check the patient's name band, but we all know that many times they are in a rush and the name band is not checked carefully. Be sure to check the patient's wrist band for name and patient admission number. Be sure to accurately label all specimens obtained with the patient's name, admission number, and time obtained. Also be sure to identify the source of the specimen, such as blood, sputum, wound, arterial blood, etc.

Many busy laboratories today, receive a very large number of specimens that are not labeled at all, or are improperly labeled. This places a huge burden on the laboratory and upon the patients. Improperly labeled specimens must be discarded. This means a tremendous waste of time and money for the facility and for the patients. In addition, the patient must have the specimen drawn again. This could lead to delays in treatments [7-9]. Every hospital is different in their procedure for handling specimens. However, there are some common factors that should be considered. In the end, always follow the procedure at your hospital. When in doubt about a lab test or diagnostic procedure, consult your laboratory procedure manual or contact the lab or the department responsible for the test. In most cases, they are more than glad to inform you concerning any special considerations needed for a test or procedure.

Quantity of Samples:

The amount of the sample needed depends upon many factors. Each lab is different in the amount of blood or other body fluid or tissue required to perform the analysis. Generally speaking, if the blood is run using modern automated analyzers, the amount of blood may be 10 ml or less for each test. If the tests are run individually, or if the tests are complicated, larger quantities of blood may be needed[9]. The quantity of the sample usually dictates the method of collection or collection procedure. The overall goal is to get the required amount of blood. A single glass or disposable plastic needle and syringe may be used to obtain a small sample of 10-20 ml of whole blood. This amount is usually sufficient to perform one or two tests. However, for a series of tests, more blood is needed[10].

In order to avoid multiple veinpunctures, it is usually best to use an evacuated blood tube system such as the "Vacutainer" or

"Corvac" collection systems. These systems are very popular for drawing multiple samples of blood. They use blood tubes with a rubber stopper and a vacuum inside the tube. These tubes are manufactured in a variety of sizes and with a variety of additives in the evacuated tubes. Color-coded tubes indicate the different additives in the tube. The vacuum in the tube causes just the correct volume of blood to be drawn into the tube. The tubes are consecutively used to draw blood from one veinpuncture site, thereby negating the use of multiple punctures. This, of course, is under ideal conditions. We assume that correct technique is being used. We also assume that the patient's vein will support multiple samples being drawn at one time from one location. These tubes hold 2-20ml of blood in each tube[9-10]. In infants and children, microanalysis techniques allow sampling of capillary blood through micropipettes or capillary tubes. This technique is used when the patient is an infant/child or has severe burns and/or has absolutely no useable veins to draw from. This technique is timeconsuming and very expensive. Therefore, if possible, the multiplesample technique is preferred. Micropipettes hold from 30 ul to 50 ul of serum or plasma [10].

Safeguards for vein puncture:

1. In case of syncope, be sure to place patient in a comfortable but "safe" position. The most common position is sitting or lying down.

2. If using a needle and syringe to draw blood, be sure not to inject air into the vein. Be sure to have the plunger completely depressed before you start the procedure.

3. Avoid drawing blood in an extremity used for infusing intravenous solutions. The solutions will dilute the blood directly proximal to the IV site. You may draw blood (below) distal to the IV site, being sure not to draw too close to the IV site. You are too close, if your venipuncture activities touch the IV site or interfere with the infusion of the IV in any way. Also be sure not to contaminate the IV site while drawing blood near the site [10].

Laboratory requisition:

The following items should be included on the lab requisition:

1. Full name: middle name should be included to avoid confusion in the event that there is another patient with the same first and last name.

2. Location: inpatient, room, unit, outpatient, address.

3. Patient's identification number: this identification can be very useful for instance in the blood bank.

4. Patient age and sex: in evaluating laboratory results, the reference values may differ for age and sex; disease prevalence may be age- or sex-linked.

5. Name(s) of the physician(s): name all of the physicians on the case; "panic values" should be called to the attention of the physician ordering the test; a physician may have some specific test guidelines for his patients.

6. Name of the test and the source: reference values may be different for the different biologic specimens (e.g., serum and CSF glucose); in microbiology, it is essential to know the source of the swab.

7. Possible diagnosis: essential for evaluating laboratory results and selecting appropriate methodology; (media selection in microbiology).

8. The date and time the test is to be done: some tests must be scheduled by the laboratory; blood transfusions may require ample advance notice; patient preparation and diet regulations need to be considered.

9. Special notation: provide relevant information to assist the

laboratory--e.g., medications taken; for hormone assay, the point in the menstrual cycle when the specimen was obtained; for microbiology, the patient's sensitivity to drugs.

Diagnosis:

It is very important to identify any patient condition or activity that might affect the lab test or diagnostic test being performed. Always be sure to identify anything that might be relevant to that particular test. Now, you might say that this is a very broad statement; and you are very correct. You as the nurse, however, should be alert to conditions that could possibly influence tests. For example, the patient's temperature can affect certain tests [11]. Some patients are taking supplementary oxygen. Some patients might have just eaten a very large meal.

Of course, it is impossible to memorize every single lab test, along with every single factor that might affect these tests. Therefore, it is wise for every nurse to simply make note of any unusual conditions present during the test. For example, your patient has a 24-hour urine test ordered. When you begin the collection of the test, you will note the time in your nurse's notes. Therefore, when you mention that you have started the collection, also mention any other unusual conditions[10-11].

Biochemistry:

Blood chemistry testing is defined simply as identifying the numerous chemical substances found in the blood. The analysis of these substances will provide clues to the functioning of the major body systems. Most nurses are concerned with the fact that many blood chemistry tests are performed on the serum derived from whole blood. Serum, of course, is the liquid remaining after whole blood has clotted in the sample tube. Some blood chemistry tests are performed on other parts of blood as well [12].

Many laboratories now use automated electronic systems, such as the Sequential Multiple Analyzer (SMA) 12/60 and the Sequential Multiple Analyzer with Computer (SMAC). These machines are used for blood chemistry procedures, blood banking, serological procedures, and bacteriologic procedures. These systems perform blood studies rapidly, economically, and comprehensively. They can detect unsuspected abnormalities and indicate the need for additional tests [11-12]. The SMA 12/60 can make 12 determinations on 60 serum specimens in one hour. The SMAC can perform 20 to 40 biochemical determinations on 120 serum specimens in one hour. The SMAC can perform complete blood chemistry profiles in a short time and on very little blood. Prior to taking the blood sample, the nurse should inform the patient about the test(s) to be performed and the preparation for the test. You should:

- 1. define and explain the test
- 2. state the specific purpose of the test
- 3. explain the procedure
- 4. discuss test preparation, procedure, and posttest care

Some of the more common tests require no special preparation. However, some blood chemistry tests will have specific requirements such as dietary restrictions or medication restrictions. For some tests, such as hormones, stress should be avoided prior to the test. Be sure to inform the patient of any special preparation prior to the vein puncture and any posttest care needed.

Traditionally, laboratory practice can be divided into 3 phases (preanalytical, analytical, and post-analytical). All 3 phases of the total testing process can be targeted individually for improving quality, although it is well published that most errors occur in the pre- and post-analytical phases. Previous days Analytical errors was Errors in clinical laboratories (including pre- and post-analytical phases), errors in the total testing process (including pre-pre- and postpost-analytical phases) and now testing related diagnostic process. Laboratory studies confirmed these data and, currently, pre-analytical errors or more accurately pre-pre-analytical errors are estimated to account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from problems in patient preparation, and sample collection, transportation, preparation for analysis and storage. This inspired a patientcentred evaluation of errors in laboratory testing and an increased concern to identify weaknesses and vulnerability in procedures and processes, so that corrective and preventive actions can be activated before any adverse event or patient harm may occur. A further step in the journey towards a better understanding of the issue is the recent proof that errors in laboratory medicine are part of a much wider issue, commonly known as "diagnostic error", thus definitively linking laboratory-associated errors to patient safety problems.

In the field of laboratory medicine, previous studies [13-16] published that the total testing process error rate ranges widely from 0.1% to 3.0%. In previous studies [16] done in laboratory error rates declined over 10 years from 0.47% in 1977 to 0.33% in 2007. A similar declining trend has been seen specifically in analytical errors. The analytical variability is now frequently less than 1/20th of what it was 40 years ago. The major focus in health care is placed on incident reporting for several medical conditions with lesser effort devoted to translating this noteworthy practice into laboratory diagnostics. If, in fact, laboratory errors are being underreported, then current statistics reveal only a small portion of the medical errors actually taking place. There is an urgent need to establish a reliable policy of error recording, possibly through informatics aids,[16]and settle universally agreed "laboratory sentinel events" throughout the total testing process, which would allow gaining important information about serious incidents and holding both providers and stakeholders accountable for patient safety. Some of these sentinel events have already been identified, including inappropriate test requests and patient misidentification (pre-analytical phase), use of wrong assays, severe analytical errors, tests performed on unsuitable samples, release of lab results in spite of poor quality controls (analytical phase), and failure to alert critical values and wrong report destination (post-analytical phase).

Common Problems of Analytic Phase are Test interference –false positive and negative results, Send out testing –delayed results; results not interfaced to LIS; results don't reach current provider, Cytology & pathology error 2- 4% missed or wrong malignancies, Generally all these errors Risks are increasing for pre and post analytical, New trainees seem increasingly less interested in the lab, The distance between the lab and clinicians is growing.

Solutions for the clinical lab are Focus on finding and fixing pre and post analytical errors, Identify a clinical liaison person Simplify test ordering, Use order sets, Use reflexive testing, Address cognitive error, Get second opinions, Improve test reporting: Better comments, display trends.

According to recent data from malpractice claims, diagnostic errors appear to be the most common, most costly and most dangerous of medical mistakes both in inpatients and outpatients [13-14]. Failure in the ordering of appropriate laboratory test and the application of laboratory test results are major contributors to diagnostic errors, along with residual problems in test performances (analytical errors) [14]. Therefore, the main message is the need to improve the quality of laboratory services, avoiding errors and improving patient safety [15-16]. The use of a consensually-defined list of evidence-based studies applied in the accreditation programs of clinical laboratories according to the current International Standard (ISO 15189:2012) is an effective tool for improving quality, decreasing the risk of errors and increasing patient safety.

The purpose of the Review what we discussed in this article is to systematically examine the information of case details, sample collection procedures and assays that optimize the use of these additional case reviews inorder to reduce interpretive errors or descrepancies.

CONCLUSION

While many areas of health care are still struggling with the issue of patient safety, laboratory diagnostics has always been a forerunner in pursuing this issue. Patient safety emphasizes the reporting, analysis, and prevention of medical errors that often lead to adverse events. Besides carrying serious harms to patient health. So Laboratory errors can no longer be seen as inevitable, but it can be actively streamlined and prevented. Laboratorians and clinicians should forge stronger links between diagnostic testing and patient outcomes. Without those links, the clinical laboratory will continue to be driven primarily by cost, volume and process measures.

REFERENCES

- Springhouse Handbook of Diagnostic Tests, 2nd edition, Springhouse Co., 1999. 2. Brunner, L.S. & Suddarth, D.S., The Lippincott Manual of Nursing Practice, JB Lippincott, 1999.
- 3. Buckingham, Alan, Arterial Blood Gases Made Simple, Nursing Life, Nov/Dec 1994.
- Δ Diagnostic Tests Handbook, Springhouse, Penn. Intermed Communications, 1994 Fischbach, F., A Manual of Laboratory diagnostic Tests, Philadelphia, Lippincott, 5. 1998
- 6. Kee, Joyce LeFever; Laboratory and Diagnostic Tests with Nursing Implications,
- Appleton-Century-Crofts, 1991. Long and Phipps, Essentials of Medical Surgical Nursing, Mosby Co, 1990. 7.
- Luckman, J., & Sorensen, K.C., Medical-Surgical Nursing, 2nd ed., Philadelphia, 8. Saunders, 1990.
- 9. Manual of Radiology Service, Wilmington Delaware, Veterans Administration Center, 1990.
- 10. Phipps, W.J., et. al., Schafer's Medical-Surgical Nursing, St Louis, Mo., Mosby, 1991.
- Wallach, Jacques, Handbook of Interpretation of Diagnostic Tests, Lippincott-11.
- Raven publishers, Philadelphia, 1998. Whitehouse, W.M., (Ed.) The Yearbook of Diagnostic Radiology-1991, Chicago, Year Book Med Publ, revised 1991. 12. 13.
- Plebani M, Chiozza ML, Sciacovelli L. Towards harmonization of quality indicators in laboratory medicine. Clin Chem Lab Med 2013;51:187-195. Plebani M, Astion ML, Barth JH, Chen W, de Oliveira Galoro CA, Escuer MI, et al. 14.
- Harmonization of quality indicators in laboratory medicine. A preliminary consensus. Clin Chem Lab Med 2014;52: 951-958. Plebani M, Laposata M, Lundberg GD. The brain-to-brain loop concept for
- 15. laboratory testing 40 years after its introduction. Am J Clin Pathol 2011;136:829-833.
- A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today-Julie A. Hammerling, MSH, MS, MLS(ASCP)-Lab Med. 2012;43(2):41-44. 16.